IN THE CLAIMS

Kindly replace claims 2, 6, 10, 16-19, 28 and 29 by the following claims.

D1 Sub E1

2. (twice amended) A method according to claim 28, wherein step (α) is carried out in an anhydrous medium.

Sub E1 D2 Cont

6. (thrice amended) A method according to claim 28, wherein the nanodispersion comprises as component

(a) a phospholipid, a hydrated or partially hydrated phospholipid, a lysophospholipid, or mixtures thereof.

Sub E1 D3 Cont

10. (thrice amended) A method according to claim 28, wherein the nanodispersion comprises at least one component (b) selected from the group consisting of polyethoxylated sorbitan fatty acid esters, polyethoxylated fatty alcohols, polyethoxylated fatty acids, polyethoxylated vitamin E derivatives, polyethoxylated lanolin and derivatives thereof, polyethoxylated fatty acid partial glycerides, polyethoxylated alkylphenols, polyethoxylated fatty alcohols and salts thereof, polyethoxylated fatty amines and fatty acid amides and polyethoxylated carbohydrates.

Sub E1 Cont

16. (twice amended) A pharmaceutical liquid formulation in the form of an injectable solution, infusion solution, drops, spray, aerosol, emulsion, lotion, suspension, drinking solution, gargle or inhalant, which comprises a nanodispersion as defined in claim 29.

D4

17. (twice amended) A pharmaceutical semisolid formulation in the form of an ointment, oil-in-water emulsion, water-in-oil emulsion, gel, lotion, foam, paste, suspension, ovula or plaster, which comprises a nanodispersion as defined in claim 29.

18. (twice amended) A pharmaceutical solid formulation in the form of a tablet, coated tablet, capsule, granules, effervescent granules, effervescent tablet, lozenge, sucking and chewing tablet, suppositories, implant, lyophilisate, adsorbate or powder, which comprises a nanodispersion as defined in claim 29.

19. (twice amended) A matrix- or membrane-controlled pharmaceutical application system in the form of an oros capsule, transdermal system or injectable microcapsule, which comprises a nanodispersion as defined in claim 29.

28. (thrice amended) A method of preparing a pharmaceutical formulation of a lipophilic pharmaceutical active agent in the form of an aqueous nanodispersion, which steps consist essentially of

(α) mixing the components

(a) 0.1 to 30 % by weight of a phospholipid,

(b) 1 to 50 % by weight of a polyoxyethylene coemulsifier,

(c) 0.1 to 80 % by weight of a lipophilic component which comprises a natural or synthetic or a partially synthetic C_4-C_{18}triglyceride, and a lipophilic pharmaceutical active agent, in which aqueous nanodispersion any pharmaceutically active agent is lipophilic and is always present in component (c), and

(d) 0.63 to 14.2 % by weight of ethanol, with the proviso that the sum of (a), (b), (c) and (d) is 100 % by weight,

in conventional stirring apparatus until a homogeneous clear liquid is obtained and

(β) adding the liquid obtained in step (α) to a water phase, wherein (β) is carried out in the absence of high shear or cavitation forces, and wherein the particles in the nanodispersion have an average diameter <50 nm.

29 (thrice amended). An aqueous nanodispersion of a lipophilic pharmaceutical active agent, which consists essentially of

(a) 0.1 to 30 % by weight of a phospholipid,

(b) 1 to 50 % by weight of a polyoxyethylene coemulsifier,

(c) 0.1 to 80 % by weight of a lipophilic component which comprises a natural or synthetic or a partially synthetic C_4-C_{18}triglyceride, and a lipophilic pharmaceutical active agent, in which aqueous nanodispersion any pharmaceutically active agent is lipophilic and is always present in component (c), and

(d) 0.63 to 14.2 % by weight of ethanol, with the proviso that the sum of (a), (b), (c) and (d) is 100 % by weight, plus

(e) a water phase,

which formulation is obtainable by

Sub E' Contd

(α) mixing the components (a), (b), (c), and (d) until a homogeneous clear liquid is obtained, and

(β) adding the liquid obtained in step (α) to the water phase, wherein step (β) is carried out in the absence of high shear or cavitation forces, and whereby the particles in the nanodispersion have an average diameter <50 nm.

STATUS OF THE CLAIMS

Claims 2, 6, 10, 15-21, 24 and 28-29 were pending in this application.

Claims 2, 6, 10, 15-21 and 28-29 are rejected under 35 U.S.C. § 112, second paragraph.

Claims 2, 6, 10, 15-21 and 28-29 are now rejected under 35 U.S.C. § 102(b) as being anticipated by Weder et al., WO 96/37192.

Claims 2, 6, 10, 15-21 and 28-29 are again rejected under 35 U.S.C. § 103(a) as being unpatentable over Weder, U.S. Patent 5,997,888 in view of WO 96/37192.

Claims 2, 6, 10, 15-21 and 28-29 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 32-45 of copending application number 09/306,005.

Claims 2, 6, 10, 16-19, 28 and 29 have been amended.

Claims 2, 6, 10, 15-21, 24 and 28-29 are presented for reconsideration.

REMARKS

Contrary to the Office Action Summary, applicants respectfully point out that claim 24 is also pending. It is neither rejected nor objected to.

Claims 2, 6, 10, 16-19, 28 and 29 have been amended by replacement. No other claims have been amended. No claims have been added.